

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation of the Effect of Betamethasone on Neonatal Outcomes in Late Preterm Pregnancies

#### Protocol summary

##### Summary

Objectives: This study investigates the effect of Betamethasone on prevention of respiratory distress syndrome among neonates with gestational age of 34-36 weeks. Design: 140 pregnant women aged between 18 to 39 years who are of high risk for preterm labor in 34-36 weeks will be randomly divided into control or intervention groups (each group contains 70 participants). Setting and conduct: The intervention group and control group will receive 2 doses of 3 ml of Betamethasone and normal saline (as the placebo), respectively. Major Inclusion and Exclusion criteria: Pregnant women who are candidate for delivery in 34-36th week of gestational age with the absence of underline diseases such as diabetes or special conditions like multiple pregnancy or fetal anomalies Intervention: Receiving Betamethasone or placebo (normal saline) Main outcome measures (variables): After delivery, data including apgar score, respiratory distress syndrome and other abnormalities of the newborns will be assessed and recorded in questionnaire by neonates specialist.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014102919037N2**

Registration date: **2014-11-10, 1393/08/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-10, 1393/08/19

##### Registrant information

###### Name

Mahdieh Yousef-Zanjani

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 6004

##### Email address

yusefi.mahdieh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2013-11-22, 1392/09/01

##### Expected recruitment end date

2014-11-22, 1393/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the Effect of Betamethasone on Neonatal Outcomes in Late Preterm Pregnancies

##### Public title

Evaluation of the Effect of Betamethasone on Neonatal Outcomes in Pregnancies

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women aged between 18 to 39 years who are candidate for delivery in 34-36th week of gestational age Exclusion criteria: Delivery after 37th week of gestational age; diabetes; fetal anomalies; delivery before receiving the two doses of the drug; multiple pregnancy

##### Age

From **18 years** old to **39 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Participants will be divided into two groups (control or intervention) by randomized block design

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin university of medical sciences

**Street address**

Shahid Bahonar Boulevard

**City**

Qazvin

**Postal code****Approval date**

2014-05-11, 1393/02/21

**Ethics committee reference number**

28.20.8737

**Health conditions studied****1****Description of health condition studied**

Respiratory Distress Syndrome of Newborn

**ICD-10 code**

P22.0

**ICD-10 code description**

Hyaline Membrane Disease

**2****Description of health condition studied**

Preterm Labour and Delivery

**ICD-10 code**

060

**ICD-10 code description**

Onset (Spontaneous) of Labour Before 37 Completed Weeks of Gestation

**Primary outcomes****1****Description**

Occurrence of respiratory distress syndrome of newborn

**Timepoint**

Every 30 min up to 48 h

**Method of measurement**

Questionnaire

**2****Description**

Apgar

**Timepoint**

At birth

**Method of measurement**

Checklist

**Secondary outcomes****1****Description**

Need for newborn admission

**Timepoint**

Up to 48 h

**Method of measurement**

Questionnaire

**Intervention groups****1****Description**

First intervention group: Intramuscularly injection of 6ml of betamethasone solution (4mg/ml) (divided into two 3ml injection with a 12-hour interval), from Sahaamy-e Aam drug manufacturing company, Boroujerd, Iran, registered No. 1228030994

**Category**

Treatment - Drugs

**2****Description**

Second intervention group: Intramuscularly injection of 6ml of normal saline solution (9mg/ml) (divided into two 3ml injection with a 12-hour interval), from Daroupakhsh drug manufacturing company, Tehran, Iran, registered No. 1228057458

**Category**

Treatment - Drugs

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Kosar Obstetric and Gynecology Hospital

**Full name of responsible person**

Dr. Ezzatossadat Haj Seyyed Javadi

**Street address**

Kosar Street, Ayatollah Taleghani Boulevard

**City**

Qazvin

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Investigator

**Full name of responsible person**

Dr. Maryam Jafari

**Street address**

Kosar Hospital, Kosar Street, Ayatollah Taleghani Boulevard

**City**

Qazvin

**Grant name**

-

**Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Investigator

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kosar Obstetric and Gynecology Hospital

**Full name of responsible person**

Dr. Maryam Jafari

**Position**

Gynecology Resident

**Other areas of specialty/work****Street address**

Kosar Street, Ayatollah Taleghani Boulevard

**City**

Qazvin

**Postal code****Phone**

+98 28 3323 6374

**Fax****Email**

dr.jafari1981@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*